UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

PAUL F. DESCOTEAU, et al.,	***)***	
	)	
Plaintiffs	***)***	
	)	
v.	***)***	***Civil No. 09-312-P-S***
	)	
ANALOGIC CORPORATION, et al.,	***)***	
	)	
Defendants	***)***	

RECOMMENDED DECISION ON MOTION TO DISMISS

Defendants Analogic Corporation ("Analogic") and B-K Medical Systems, Inc. ("B-K Medical") (together, "defendants") move pursuant to Federal Rule of Civil Procedure 12(b)(6) to dismiss the two-count complaint against them on grounds that (i) as to the plaintiff Paul F. Descoteau, it is barred by the applicable statute of limitations and (ii) as to both the plaintiff and the putative class-action members, it fails to state claims of strict liability or negligent infliction of emotional distress ("NIED") with respect to which relief can be granted. *See* Defendants' Motion To Dismiss Complaint Pursuant to Fed.R.Civ.P. 12(b)(6) ("Motion") (Docket No. 10) at 1-2 & n.1.[1] For the reasons that follow, I recommend that the Motion be granted as to the plaintiff's NIED claim and otherwise denied.

I. Applicable Legal Standards

As the Supreme Court has clarified:

> While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. Factual allegations must be enough to raise a right to relief above the speculative level.

Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007) (citations omitted).

[1] As the defendants observe, *see* Motion at 1-2 n.1, the plaintiff has not to date filed a motion for class certification.

"In ruling on a motion to dismiss [under Rule 12(b)(6)], a court must accept as true all the factual allegations in the complaint and construe all reasonable inferences in favor of the plaintiffs." *Alternative Energy, Inc. v. St. Paul Fire & Marine Ins. Co.*, 267 F.3d 30, 33 (1st Cir. 2001). Ordinarily, in weighing a Rule 12(b)(6) motion, "a court may not consider any documents that are outside of the complaint, or not expressly incorporated therein, unless the motion is converted into one for summary judgment." *Id.* "There is, however, a narrow exception for documents the authenticity of which are not disputed by the parties; for official public records; for documents central to plaintiffs' claim; or for documents sufficiently referred to in the complaint." *Id.* (citation and internal quotation marks omitted).

II. Factual Background

The complaint alleges in relevant part:

Analogic is a Massachusetts corporation with its principal place of business in Peabody, Massachusetts, which at all material times did business in the state of Maine. Class Action Complaint ("Complaint"), attached to Notice of Removal (Docket No. 1), ¶ 2. B-K Medical is a Danish corporation with its principal places of business in Copenhagen, Denmark, and Wilmington, Massachusetts, which at all material times did business in the state of Maine. *Id.* ¶ 3.

The defendants are wholly involved in and responsible for the marketing, design, formulation, manufacture, sale, installation, servicing, and/or maintenance of the B-K Medical Falcon Transrectal Ultrasound Transducer Assembly, Scanner Type 2101A, rectal probe models 8808 and 8851 (collectively, "Ultrasound Transducer Assembly"). *Id.* ¶ 7. The Ultrasound Transducer Assembly is a device used in transrectal biopsy procedures. *Id.* ¶ 8. During the procedure, the rectal probe is inserted into the rectum of the patient to observe the prostate gland

for irregularities in its appearance. *Id.* Then, a spring-loaded needle is inserted through the probe and into the gland to extract small amounts of tissue for pathological testing. *Id.*

The defendants were the manufacturers and sellers of the Ultrasound Transducer Assembly, and sold the assemblies from approximately 1998 through 2006 to at least 22 U.S. Veterans Administration ("VA") hospitals nationwide, including the Togus VA Medical Center in Augusta, Maine ("Togus"). *Id.* ¶ 9.

On or about November 27, 2002, Togus purchased from the defendants a B-K Medical Falcon Transrectal Ultrasound Transducer Assembly, Scanner Type 2101A, rectal probe model 8808. *Id.* ¶ 10. During the interim period from when the device was ordered to when it was delivered on March 13, 2003, B-K Medical provided Togus with a demonstration unit of the same scanner that Togus could use to clear its backlog of biopsies. *Id.* ¶ 11.

As part of the purchase of this equipment, a company representative visited the facility to provide set-up and education to the staff of the hospital regarding the use and maintenance of the device, including methods for cleaning the rectal probes. *Id.* ¶ 12. When the new Ultrasound Transducer Assembly was delivered, a manual for its operation, maintenance, and cleaning was provided, as well. *Id.* ¶ 13. Both the oral instructions provided by B-K Medical and the operation manual given to Togus specified that cleaning of the rectal probes was to be accomplished by flushing the inner cannula of the rectal probe with a syringe filled with a mixture of detergent and water. *Id.* ¶ 14.

On February 7, 2003, the plaintiff had a prostate biopsy performed at Togus using the Ultrasound Transducer Assembly. *Id.* ¶ 15. During patient safety rounds on January 26, 2006, members of Togus' staff examined the rectal transducer and puncture guides and found that blood and fecal matter remained in the guide although the equipment had been cleaned in

accordance with the manufacturer's instructions. *Id.* ¶ 16. A subsequent VA investigation concluded that the cleaning instructions provided by the defendants were inadequate. *Id.* ¶ 17.

The VA subsequently conducted a systemwide review of the procedures governing cleaning of the probes and identified 22 medical centers, including Togus, that used both an Ultrasound Transducer Assembly, either model 8808 or 8551, and cleaned those transducers as instructed by the defendants, that is, without using a brush. *Id.* ¶ 18.

Approximately 23,000 veterans nationwide, including 528 at Togus, were identified as having undergone biopsy procedures with an Ultrasound Transducer Assembly and as having potentially been exposed to HIV, Hepatitis B, Hepatitis C, and other bloodborne viral pathogens as a result of improper and inadequate cleaning instructions. *Id.* ¶¶ 19-20.

By letter dated April 14, 2006, the VA notified the plaintiff that the equipment used to perform the biopsy on February 7, 2003, might not have been satisfactorily sterilized or disinfected and that he might have been exposed to Hepatitis B, Hepatitis C, or HIV. *Id.* ¶ 21. At or about the same time, similar letters were sent to each of the 23,000 veterans, including the 528 at Togus identified as having potentially been exposed to those pathogens. *Id.* ¶ 22. The plaintiff and the other affected veterans were counseled to immediately schedule testing procedures to determine if they had contracted any of these life-threatening conditions. *Id.* ¶ 23.

The plaintiff returned to Togus on April 27, 2006, and was subjected to testing for Hepatitis B, Hepatitis C, and HIV. *Id.* ¶ 24. He experienced emotional and mental pain and anguish from the period of time running from when he was first notified that he might be infected, through the testing and counseling process, to when he was finally told of his negative results. *Id.* ¶ 25. He has lost wages resulting from having to miss work to take part in a testing process that he would not have had to endure but for the defendants' actions. *Id.* ¶ 26. On or

about May 11, 2006, the plaintiff was told that his results were negative for Hepatitis B, Hepatitis C, and HIV. *Id*. ¶ 27.

The plaintiff's claims are typical of those of the putative class of the approximately 528 veterans identified as having undergone biopsy procedures at Togus with an Ultrasound Transducer Assembly and as having potentially been exposed to bloodborne pathogens as a result of improper and inadequate cleaning instructions. *Id*. ¶ 32. Each of those individuals (i) underwent the same single medical procedure, a prostate biopsy, using the B-K Medical equipment, (ii) was potentially exposed to bloodborne viral pathogens such as HIV, Hepatitis B, and Hepatitis C because of improper and inadequate cleaning instructions and training, (iii) suffered emotional distress upon learning of the potential exposure to those pathogens for a discrete time, specifically from when he was informed of the possible infection to when he received the negative results, (iv) experienced the physical pain and discomfort of the blood testing to determine whether he had contracted any of those conditions as a result of that exposure, and (v) ultimately was determined not to be infected. *Id*.

III. Discussion

The plaintiff, on behalf of himself and others similarly situated, brings claims for strict liability, alleging that the B-K Medical equipment was defective and unreasonably dangerous when sold to Togus because it lacked adequate warning or instructions for cleaning to prevent patient exposure to bloodborne viral pathogens (Count I), *see id*. ¶ 40, and for negligence as a result of which he and others similarly situated suffered harm (Count II), *see id*. ¶ 49.[2]

[2] Count II of the complaint is styled as a claim for "negligence." *See* Complaint ¶¶ 46-51. The defendants construe it as a NIED claim. *See* Motion at 2 & n.2. However, the plaintiff clarifies that it is a claim for both NIED and negligently caused physical harm. *See* Plaintiff's Objection to Defendant's Motion To Dismiss ("Objection") (Docket No. 27) at 8. Count II fairly can be read as the plaintiff suggests, *see* Complaint ¶¶ 46-51, and that is how I construe it.

The defendants seek dismissal of (i) the plaintiff's claims on the ground that they are time-barred and (ii) the claims of the plaintiff and putative class members on the ground of failure to state causes of action for either strict liability or NIED. *See* Motion at 1-2 & n.1.

A. Statute of Limitations: Accrual of Causes of Action

As a threshold matter, the defendants contend that the plaintiff failed to file the instant complaint within six years of accrual of his causes of action as required by 14 M.R.S.A. § 752, barring maintenance of his suit. *See* Motion at 4-7; 14 M.R.S.A. § 752 ("All civil actions shall be commenced within 6 years after the cause of action accrues and not afterwards, . . . except as otherwise specially provided."). The complaint was filed in the Maine Superior Court, Kennebec County, on June 3, 2009. *See* Notice of Removal at 1; Complaint.

Both sides agree that (i) in this diversity action, Maine law applies, (ii) there is no statutory definition of the word "accrues," necessitating its judicial interpretation, and (iii) the Law Court has held that "a cause of action in tort is deemed to accrue when the plaintiff sustains a judicially cognizable injury: the moment when a wrongful act produces an injury for which the plaintiff is entitled to seek judicial vindication." Motion at 4 (quoting *Myrick v. James*, 444 A.2d 987, 994 (Me. 1982)); Objection at 3 & n.1.

Nonetheless, the parties part ways on the application of those principles to the instant claims. The defendants argue that the plaintiff's claims accrued on February 7, 2003, the date of his prostate biopsy. *See* Motion at 5. They reason that, as a result of their alleged wrongdoing, the plaintiff then potentially was exposed to certain diseases, a judicially cognizable injury for which he was entitled to seek vindication. *See id.* The plaintiff contends that his claims did not accrue until April 14, 2006, when he first was notified by the VA that he might be infected with a life-threatening disease, and April 27, 2006, when he underwent otherwise unnecessary

diagnostic testing. *See* Objection at 3. He reasons that until then he had no reason to suspect, let alone fear, that he might be infected with a communicable disease nor to obtain related diagnostic testing. *See id*. at 3-4.

A party pleading the statute of limitations as an affirmative defense bears the burden of establishing that a cause of action is time-barred. *See, e.g., Nuccio v. Nuccio*, 673 A.2d 1331, 1333 (Me. 1996). The defendants fall short of so doing, relying on an argument that misapprehends the nature of the plaintiff's claims. The plaintiff sues not because of a potential exposure to deadly pathogens, but rather because of the emotional injury that he suffered upon learning that he might have been so exposed, and the pain and discomfort that he experienced upon undergoing otherwise needless diagnostic testing.

Put differently, while the defendants' alleged wrongful acts may have occurred in 2003, they did not produce the injuries of which the plaintiff complains until April 2006. Only then did he have an entitlement to seek judicial redress for those injuries. *See, e.g., Bernier v. Raymark Indus., Inc*., 516 A.2d 534, 542-43 (Me. 1986) (holding that plaintiffs' claims accrued not when they inhaled asbestos fibers, but rather when there was a manifestation of resultant physical injury; observing, "The actionable harm is the manifestation of disease in the body, not the exposure to the potentially hazardous substance or some more abstract invasion of a person's legally protected interests."). Because the plaintiff's causes of action did not accrue until April 2006, his complaint was timely filed in June 2009.[3]

[3] I need not and do not reach the defendants' additional argument that the court should decline to apply the so-called "discovery rule," which would be implicated only if the plaintiff's claims were otherwise untimely. *See* Motion at 5-7.

B. Strict Liability Claim

The defendants next seek to dismiss the plaintiff's strict liability claim on the ground that it insufficiently alleges physical harm, a prerequisite to liability pursuant to Maine's strict liability statute, 14 M.R.S.A. § 221. *See* Motion at 7-8. Section 221 provides, in relevant part:

> One who sells any goods or products in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to a person whom the manufacturer, seller or supplier might reasonably have expected to use, consume or be affected by the goods, or to his property, if the seller is engaged in the business of selling such a product and it is expected to and does reach the user or consumer without significant change in the condition in which it is sold.

14. M.R.S.A. § 221.

The defendants acknowledge that the plaintiff claims that he and others similarly situated "[e]xperienced the physical pain and discomfort of the blood testing" done to determine whether they had contracted any bloodborne illness as a result of the potential exposure to viral pathogens. *See* Motion at 8; Complaint ¶ 32(d). However, they argue that this falls far short of stating a claim of physical harm or impairment, deeming "preposterous" any claim that a routine, voluntary drawing of blood for medical testing purposes can give rise to an actionable claim for personal injury. *See* Motion at 8. In any event, they contend, the plaintiff fails to allege that any physical harm was actually or proximately caused by use of the prostate biopsy equipment. *See id.*; *see also, e.g.*, *Ames v. Dipietro-Kay Corp.*, 617 A.2d 559, 561 (Me. 1992) ("In order to recover under either a product liability or a negligence theory, it is essential that the plaintiff prove that a product's defective design or the defendant's negligent conduct proximately caused the plaintiff's injuries.").

The plaintiff rejoins that he adequately alleges that (i) he and others similarly situated suffered physical harm when they underwent recommended diagnostic testing that entailed the drawing of their blood by a syringe, a physical invasion of their persons by a sharp object, and (ii) this harm was proximately caused by the defendants' alleged conduct. *See* Objection at 7-8. He reasons that the extent of injury bears on the amount of damages, not on whether the complaint states a claim for strict liability. *See id*. at 8.

The plaintiff has the better argument. Section 221, on its face, imposes liability for "physical harm" to persons or to their property without qualification as to the quantum of harm caused. *See* 14 M.R.S.A. § 221. The defendants cite no authority in support of the proposition that a needle stick or blood draw constitutes insufficient physical harm, as a matter of law, to support a strict liability claim, and I find none. Indeed, I am unable to find any authority for the broader proposition that a plaintiff must allege physical harm of a greater than *de minimis* level to state such a claim.[4]

The defendants fare no better in suggesting that the complaint fails to allege that their conduct proximately caused the physical harm in question. A cause is "proximate" if "in natural and continuous sequence, unbroken by an efficient intervening cause, [it] produces the injury and

[4] The defendants point out that "physical harm" is defined in the Restatement (Third) of Torts as "the physical impairment of the human body or of real property or tangible personal property[.]" Motion at 7 (quoting Restatement (Third) of Torts: Liability for Physical and Emotional Harm § 4). They argue that a needle stick performed as part of a routine medical procedure does not fit this definition. *See id*. Assuming that it is appropriate to look to the Restatement (Third) of Torts in construing Maine's strict liability statute, *see Moores v. Sunbeam Prods., Inc*., 425 F. Supp.2d 151, 156 (D. Me. 2006) ("Sunbeam concedes, probably wisely, that Maine [strict liability] law incorporates section 3 of the Restatement (Third) of Torts: Products Liability"); *Doe v. Solvay Pharms., Inc*., 350 F. Supp. 2d 257, 267 (D. Me. 2004), *aff'd*, 153 Fed. Appx. 1 (1st Cir. 2005) ("[B]ecause the Maine Legislature modeled its strict liability statute on § 402A of the Restatement (Second) of Torts, Maine courts have looked to the Restatement for interpretive guidance."), the reference does not help the defendants. The phrase "physical impairment of the human body" is itself defined to include "physical injury." Restatement (Third) of Torts: Liability for Physical and Emotional Harm § 4. Comment c to section 4 clarifies: "[A]ny level of physical impairment is sufficient for liability; no minimum amount of physical harm is required. Thus, any detrimental change in the physical condition of a person's body or property counts as a harmful impairment; there is no requirement that the detriment be major." *Id*. cmt. c. A needle puncture and withdrawal of blood fairly can be characterized as at least a minor physical injury or a minor detrimental change in the physical condition of one's body.

without [it] the result would not have occurred." *Ames*, 617 A.2d at 561 (citation and internal quotation marks omitted). "However, the mere occurrence of an intervening cause does not automatically break the chain of causation stemming from the original actor's conduct." *Id.* "In order to break that chain, the intervening cause must also be a superseding cause, that is, neither anticipated nor reasonably foreseeable." *Id.*

The plaintiff alleges that the letter that he, and others similarly situated, received from the VA stated that the equipment used to perform the biopsy may not have been satisfactorily sterilized or disinfected, that they might have been exposed to Hepatitis B, Hepatitis C, or HIV, and that they were "counseled to immediately schedule testing procedure[s] to determine if they had contracted any of these life threatening conditions." Complaint ¶¶ 21-23. After receiving that letter, the plaintiff returned to Togus to undergo diagnostic testing. *See id.* ¶ 24. In that scenario, his decision to undergo testing was not merely a voluntary act, as the defendants suggest, *see* Defendants' Reply Memorandum in Support of Motion To Dismiss Complaint ("Reply") (Docket No. 28) at 3-4, but rather the natural result of their alleged conduct, but for which the testing would not have occurred.

C. NIED Claim

The defendants finally seek dismissal of the plaintiff's negligence claim, arguing that the complaint fails to allege the existence of a duty to avoid causing emotional harm. *See* Motion at 8-10. The plaintiff rejoins that:

1. He alleges that the defendants' negligence caused physical, as well as emotional distress. *See* Objection at 8. The defendants themselves acknowledge that every person or entity has a duty to act reasonably to avoid causing physical harm to others. *See id.* at 8-9; *see also* Motion at 9; *Curtis v. Porter*, 2001 ME 158, ¶ 18; 784 A.2d 18, 25.

2. A claim for NIED is available when, as here, a plaintiff alleges the commission of a separate tort. *See* Objection at 8-9. The plaintiff alleges both a failure to warn for which he contends that the defendants should be strictly liable and negligence causing physical harm. *See id*.

3. The Law Court has recognized that doctors, social workers, and hospitals, among others, have a special relationship with patients and a duty to avoid causing them emotional harm. *See id*. at 11-12. In this case, as well, public policy favors the recognition of a special relationship between a manufacturer or seller of a medical device and a patient, given a patient's vulnerability and reposing of trust not only in his or her doctor but also in the medical devices used for treatment and diagnosis. *See id*.

To the extent that the plaintiff asserts a claim of negligence resulting in physical harm, the defendants articulate no compelling reason why the complaint fails to state a claim as to which relief can be granted. *See* Motion at 8-10; Reply at 4-5.[5] Accordingly, as to that aspect of Count II, the motion to dismiss should be denied.

However, to the extent that the plaintiff asserts a NIED claim, the defendants argue persuasively that his allegations on behalf of himself and others similarly situated fail to establish any entitlement to relief.

The Law Court has "recognized a duty to act reasonably to avoid emotional harm to others in very limited circumstances: first, in claims commonly referred to as bystander liability actions; and second, in circumstances in which a special relationship exists between the actor and the person emotionally harmed." *Curtis*, 2001 ME 158, ¶ 19; 784 A.2d at 25 (footnotes omitted).

[5] The defendants argue that the complaint states no plausible claim for physical injury. *See, e.g.*, Reply at 4-5. Yet, as noted above, the plaintiff alleges physical injury in the form of the pain and discomfort of diagnostic procedures to determine whether he had contracted any of the diseases to which he was potentially exposed. The defendants offer no authority in support of the proposition that, for purposes of either a strict liability or a negligence claim, physical injury must be of a certain magnitude to state a claim upon which relief can be granted.

"Special relationships" have been recognized, for NIED purposes, in cases involving, *inter alia*, a physician and a patient, a hospital and the family of a deceased patient, and a psychotherapist and a patient. *See, e.g., Fiacco v. Sigma Alpha Epsilon Fraternity*, 484 F. Supp.2d 158, 177 (D. Me. 2007), *aff'd*, 528 F.3d 94 (1st Cir. 2008).

The Law Court has "also held that a claim for negligent infliction of emotional distress may lie when the wrongdoer has committed another tort." *Curtis*, 2001 ME 158, ¶ 19; 784 A.2d at 26. "On the other hand, when there can be no recovery for emotional harm caused by the separate tort, as is the case in a few limited instances, such as negligent misrepresentation claims, a plaintiff may not circumvent that restriction by alleging negligent infliction in addition to the separate tort." *Id*.

This is not a bystander liability case. While the plaintiffs allege two separate torts, namely, a failure to warn for which they contend that the defendants should be held strictly liable and negligence causing physical harm, neither cause of action affords recovery for emotional distress. *See, e.g.*, 14 M.R.S.A. § 221 (sellers subject to liability "for physical harm thereby caused"). The plaintiff cannot look to the allegation of a NIED claim to supply emotional distress damages unavailable on the two predicate tort claims. *See Curtis*, 2001 ME 158, ¶ 19; 784 A.2d at 26.

Therefore, there can be recovery, if at all, on a NIED claim only to the extent that there exists a "special relationship" between the defendants and the plaintiff. The defendants assert, and my research corroborates, that the Law Court has not to date recognized a "special relationship" for purposes of NIED claims between a manufacturer or seller of medical equipment and an end user, or patient. *See* Motion at 9-10. This state of affairs, in itself, counsels against a finding in the plaintiff's favor. *See, e.g., Veilleux v. National Broad. Co.*, 206

F.3d 92, 131 (1st Cir. 2000) (observing that Law Court "has proceeded cautiously in determining the scope of a defendant's duty to avoid inflicting emotional distress"; stating, "we are reluctant to expand this relatively undeveloped doctrine beyond the narrow categories addressed thus far"); *Montgomery v. American Auto. Ins. Co*., No. 06-cv-116-GZS, 2006 WL 2708623, at *2 (D. Me. Sept. 20, 2006) (noting that, in the absence of a ruling by the Law Court recognizing a special relationship between an insurer and an insured for purposes of a NIED claim, this court had declined invitations to recognize such a relationship).

In any event, the plaintiff fails to make a persuasive case that the Law Court likely would recognize the special relationship for which he advocates. Doctors, psychotherapists, and hospitals deal directly with patients and their families. A patient typically has no relationship with the manufacturer or seller of a medical device. Indeed, the plaintiff does not allege that he or others similarly situated even were aware of the identity of either defendant prior to April 2006. *See generally* Complaint.[6]

The allegations of the complaint, construed in the light most favorable to the plaintiff, fall short of setting forth circumstances in which either defendant owed the plaintiff, or others similarly situated, a duty to avoid causing emotional distress. Count II hence fails to state a claim for NIED as to which relief can be granted.

IV. Conclusion

For the foregoing reasons, I recommend that the Motion be **GRANTED** as to Count II to the extent that it sets forth a claim for NIED, and otherwise **DENIED**.

[6] The plaintiff cites *Wallace v. Coca-Cola Bottling Plants, Inc*., 269 A.2d 117 (Me. 1970), for the proposition that the Law Court has upheld the maintenance of emotional distress claims against manufacturers of foods. *See* Objection at 12; *Wallace*, 269 A.2d at 121-22, *overruled on other grounds, Culbert v. Sampson's Supermarkets Inc*., 444 A.2d 433 (Me. 1982). However, the Law Court in *Wallace* did not consider whether a "special relationship" existed between the consumer/plaintiff and the manufacturer. *See Wallace*, 269 A.2d at 121-22.

NOTICE

A party may file objections to those specified portions of a magistrate judge's report or proposed findings or recommended decisions entered pursuant to 28 U.S.C. § 636(b)(1)(B) for which de novo review by the district court is sought within fourteen (14) days after being served with a copy thereof. A responsive memorandum shall be filed within fourteen (14) days after the filing of the objection.

Failure to file a timely objection shall constitute a waiver of the right to de novo review by the district court and to appeal the district court's order.

Dated this 21st day of January, 2010.

/s/ John H. Rich III
John H. Rich III
United States Magistrate Judge